UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

TPP TRIAL PLAINTIFFS' SUPPLEMENTAL BRIEF REGARDING PLANTIFFS' MOTION *IN LIMINE* NO. 16

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I. INTRODUCTION

The TPP Trial Plaintiffs file this supplemental brief regarding Motion *in Limine* 16 ("MIL 16"). For the reasons set forth herein, Defendants should be precluded from advancing their "cost of alternative, replacement drugs" theory, including that it is precluded by both on-point case law and prior decisions of this Court that constitute the law of the case. Also, Defendants' experts never disclosed the hypothetical replacement drugs and prices they advocate for, and thus will not be able to present admissible evidence for the jury to consider, thus improperly inviting the jury to engage in speculation.

A party may only present evidence relating to facts that are "of consequence in determining the action." Fed. R. Evid. 401(b); *see also* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."); Fed. R. Evid. 403 (even relevant evidence may be excluded if it results in "unfair prejudice, confusing the issues, [or] misleading the jury"); *see also United States v. Morley*, 199 F.3d 129, 133 (3d Cir. 1999) ("Evidence that is not relevant, by definition, cannot be offered for a proper purpose[.]").

II. LAW AND ARGUMENT

A. Plaintiffs Present a "Benefit-of-the-Bargain" Damages Methodology Consistent with Applicable Law and the Court's Prior Rulings

Plaintiffs straightforwardly seek to recover their paid expenditures for the Defendants' at-issue VCDs, *viz.*, the difference between what they were promised

(non-contaminated, cGMP-compliant valsartan) and what they actually received (contaminated adulterated VCDs that did not meet compendial standards and were not made in a cGMP-compliant manner). Plaintiffs' theory does not in any way implicate the cost of alternative replacement drugs.

Consistent with Plaintiffs' theory, Dr. Conti's damages calculation is quantified as the difference between the "full price paid" for the pills and zero "since the pills lack economic value." . (*See* Conti 2/3/23 Rep., at Paras. 7-8) (Dkt. No. 2633 (Ex. 3 thereto))).) Dr. Conti explains her methodology and provides full support for why her methodology is reliable and grounded in principles of economics. Indeed, Judge Kugler already held at class certification that Dr. Conti was well-qualified and that her opinions are based on a reliable methodology that was reliably applied to the facts of this case. (Dkt. No. 2261 at 86-89.)

Dr. Conti's damages methodology is also guided by applicable law. Damages calculated as the difference between amounts paid for Defendants' VCDs as represented versus the value of what was actually received is a standard measure referred to as the "benefit-of-the-bargain."[1] *Coghlan v. Wellcraft Marine Corp*., 240

[1] A closely related damages methodology is the "out-of-pocket" methodology, which as discussed below, measures the difference between the price paid and the actual value received at the time of purchase. (*See, e.g.,* Defs' Omnibus MSJ, at 36 (Dkt. No. 2562-1).) The *only* difference between the two theories (*i.e.,* benefit-of-the-bargain *versus* out-of-pocket) is that under benefit of the bargain, the injured party, in addition to seeking the difference between the price paid and actual value

F.3d 449, 452 (5th Cir. 2001) ("'benefit of the bargain' is a standard method for measuring damages in fraudulent representation and certain contract cases. The benefit of the bargain measure of damages is neither novel nor exotic."); *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 281 (3d Cir. 2018) ("Under the benefit of the bargain theory … [t]he economic injury is calculated as the difference in value between what was bargained for and what was received." (emphasis added)); s*ee also* MTD Op. 2, at 8-15 (citing and discussing the *Talcum Powder* case)).

As Defendants have acknowledged, benefit-of-the-bargain damages apply to all relevant states' breach of warranty laws. (Defs' Omnibus MSJ, at 35 (Dkt. No. 2562-1)). Indeed, each state from Express Warranty subclasses "a"[2] (excepting Puerto Rico) and "b" have enacted identical versions of of UCC § 2-714, which all specify that that "the measure of damages for breach of warranty is the difference at the time and place of acceptance between the value of the goods accepted and the

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received, may also seek redress for any expectation of possible gain of which it was deprived on account of the breach of warranty or fraudulent conduct. Since Plaintiffs do not seek any such upside or gain damages and seek only the difference between price paid for and value of the product received (*i.e.,* Dr. Conti's economic worthlessness theory), there is effectively no difference in these two damages approaches as applied to this case.

[2] In light of the Court's summary judgment opinion finding notice satisfied as a matter of law, the parties are discussing regarding whether it is appropriate and efficient to include Express Warranty subclass "a" in this trial, an issue likely to be before the Court at the next CMC.

value they would have had if they had been as warranted[.]" Not only do these identical statutes provide a formula, they also specify that damages are to be calculated at the point of sale ("at the time and place of acceptance").[3] Consideration of "replacement drugs" (without admissible evidence, no less) deviates from this rubric, and is based on a purely hypothetical set of facts and circumstances that did not actually occur. And, as set forth *infra*, the benefit of the bargain measure also applies to the common law fraud and consumer protection law ("CPL") claims.

B. The Parties Have Agreed – and Judge Kugler Ruled – that the Appropriate Damages Methodology is a "Benefit of the Bargain" Theory

Plaintiffs have established that their damages should be calculated under a "benefit of the bargain" theory. As Judge Kugler succinctly wrote in rulings denying the Defendants' Motion to Dismiss:

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[3] *In re Gen. Motors LLC Ignition Switch Litig.*, 407 F. Supp. 3d 212, 222 (S.D.N.Y. 2019) ("[B]enefit-of-the-bargain damages should be measured … at the time of sale."); *see, e.g.*, *Nguyen v. Nissan N. Am., Inc.*, 932 F.3d 811, 822 (9th Cir. 2019) ("Plaintiff's theory of liability—that [defendant's conduct] injured class members at the time of sale—is consistent with his proposed recovery based on the benefit of the bargain."); *Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 989 (9th Cir. 2015) (benefit of the bargain damages "calculation need not account for benefits received after purchase because the focus is on the value of the service at the time of purchase"); *Victorino v. FCA US LLC*, No. 16CV1617-GPC(JLB), 2022 WL 3691642, at *3 (S.D. Cal. Aug. 25, 2022) ("under the benefit of the bargain theory, the court should not consider any post-sale conduct as it is immaterial. In this case, the benefit-of-the-bargain damages should be measured at the time of sale."); *Shulton, Inc. v. Optel Corp.*, 698 F. Supp. 61, 63 (D.N.J. 1988) ("The proper point at which to measure plaintiff's damages [under benefit of the bargain damages theory] is the time of injury."); *see also Tijerina v. Volkswagen Grp. of Am., Inc.*, No. 221CV18755BRMLDW, 2023 WL 6890996, at *9 (D.N.J. Oct. 19, 2023).

> *Plaintiffs' contend their monetary injury resulted from Defendants' failure to provide the benefit of their bargain*. Specifically, Plaintiffs argue they bargained for the benefits of a "generic equivalent [to] Diovan; a pure, unadulterated, and regulatory compliant valsartan generic drug, which would be identical to brand-name valsartan." Because the VCDs were not as Defendants represented and warranted—that is, they were adulterated, misbranded, non cGMP compliant, and illegal to sell—Plaintiffs did not receive the benefit of their bargain and suffered economic loss by receiving a worthless product.
> …
> Additionally, this theory of economic loss "would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *In re Johnson & Johnson Talcum Powder Prods. Litig*., 903 F.3d 278, 285 (3d Cir. 2018). *Under this theory, Plaintiffs seek reimbursement for the full amount paid for the VCDs, that is, their out-of-pocket expenditures*. This is not some amorphous allegation of an economic loss lacking a concrete way of calculating it. This allegation suffices for a factfinder to value Plaintiffs' purported economic injury.

(Dkt. No. 728, at 8-15 (MTD Opinion 2 discussing economic loss standing and approving Plaintiffs' benefit of the bargain damages theory (emphasis added)); *see also* Dkt. No. 775, at 20 (MTD Opinion 3 stating "[t]his Court finds that contaminated drugs are economically worthless at the point of sale" and "contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, *were never bargained for*" (emphasis added)).

Importantly, Defendants themselves agree that the benefit of the bargain damages methodology applies to the claims. (Defs' Omnibus MSJ, at 35 (conceding that all warranty states follow benefit-of-the-bargain as well as nearly all fraud

states)). Defendants similarly concede that the few jurisdictions that do not follow benefit-of-the-bargain in all fraud causes instead follow the out-of-pocket rule, which as set forth *supra* at n.1, is indistinguishable based on Plaintiffs' damages expert's methodology in this case. (*Id.*, at 36 (citing authorities submitted by Defendants at class certification).) Defendants are judicially estopped from arguing otherwise. (Dkt. No. 2778, SMO 100, at 17-18 (citing and quoting authorities).)

Plaintiffs' CPL claims, like the fraud claims, are premised on the very same misrepresentations made by Defendants as to their VCDs. *Coghlan*, 240 F.3d at 452 (stating that the "'benefit of the bargain' is a standard method for measuring damages in fraudulent representation and certain contract cases"). As Plaintiffs will set forth in their proposed jury instructions, all of the CPL jurisdictions at issue (with the exception of Louisiana for which there are no directly on-point authorities as Defendants themselves have conceded)[4] explicitly authorize benefit-of-the-bargain and/or out-of-pocket measures of damages,[5] as those are standard methodologies

[4] (*See* Dkt. No. 2261-3, at H-44 (Defendants conceding that in Louisiana no measure of damages is identified for fraud-based claims).) Given that the "benefit-of-the-bargain" measure is the standard measure, that measure should be applied to claims under the Louisiana Unfair Trade Practices Act.

[5] As set forth *supra* at n.1, the out-of-pocket damage methodology is a subset of benefit-of-the bargain damages, with the only difference being that a plaintiff can recover *lost opportunity* damages under benefit-of-the-bargain. Here, they are identical. (*See* Conti 2/3/23 Rep., at Paras. 7-8 (explaining damages methodology as the difference between the "full price paid" for the pills and zero "since the pills lack economic value" (Dkt. No. 2633 (sealed Ex. 3 thereto)). Given that Dr.

applied to these kinds of cases. This Court itself has recognized as much. *See, e.g., Cannon v. Ashburn Corp.*, No. 16cv1452-RMB, 2016 WL 7130913, at *7 (D.N.J. Dec. 7, 2016) (Bumb, C.J.) (applying the benefit of the bargain theory to a misrepresentation-based NJCFA claim, for example, and describing the measure of damages as "the difference in value between the product promised and the one received").

C. Judge Kugler's Summary Judgment Opinion Explicitly Rejected Defendants' "Replacement Drugs" Damages Theory

Defendants' response to MIL 16 cited two RICO cases to support their position. (Dkt. No. 2667, at 24-25 (citing *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 325 F.R.D. 529, 540 (D. Mass. 2017) and *Sergeants Benevolent Ass'n Health & Welf. Fund v. Sanofi-Aventis U.S., LLP*, 20 F. Supp. 3d 305, 328 (E.D.N.Y. 2014)), and counsel re-raised those authorities at the July 23 CMC. However, Defendants failed to inform the Court that Judge Kugler had already explicitly rejected this line of authority in his summary judgment opinion:

> For this argument that intervening causes necessarily reduce TPP losses, Ds rely on *Sargeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F.Supp. 3d 305 (E.D.N.Y. 2014). In *Sargeants*, the relevant claim was for violation of the federal RICO statute because of defendant Sanofi's alleged misrepresentations to physicians about the safety of its off-label drug. However, establishing RICO causation in *Sargeants* required a wholly different legal standard

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Conti's methodology does not seek lost opportunity damages available under benefit-of-the-bargain, the two theories effectively merge under the facts of this case

> than that for the claims here, which makes Ds "attenuated" theory based on *Sargeants* irrelevant and why the Court finds *Sargeants* inapposite.

(Dkt. No. 2694, SJ Op., at 61-62 (emphasis added).)

Judge Kugler continued by discussing the factually "quite similar" *Blue Cross Blue Shield Association v. GlaxoSmithKline LLC* case that likewise involved adulterated drugs that the TPP plaintiffs there contended – with Dr. Conti as damages expert – were economically worthless. 417 F.Supp.3d 351 (E.D. Pa. 2019).

In *BCBS*, the defendant "GSK argue[d] [that] [TPP] Plaintiffs cannot demand damages in the amount of the full price paid for the drugs because the calculation fails to take into account the cost of therapeutic alternatives Plaintiffs would have had to provide, … rel[ying] on *Sergeants Benevolent*[.]" *BCBS*, 417 F. Supp. 3d at 558; *see also* SJ Op., at 61-62 (Judge Kugler quoting extensively from *BCBS*).

Judge Kugler described Judge Sánchez's *BCBS* ruling as follows:

> In distinguishing *Sargeants* and *UFCW Local 1776*, the *BCBS* TPP plaintiffs clarified they had no option but to rely on Defendant GSK's statements about the safety of the Drug At Issue, which was used (not in an off-label application as in *Sargeants* but) directly for a medical condition. In using GSK's Drug At Issue in their formulary, the *BCBS* TPPs had only a yes/no option, not a nuanced choice, in relying on the drug's relative efficacy or expense, which translated into the *BCBS* TPPs blind reliance on GSK's misrepresentations about its Drug At Issue. Id. at 558-559. Judge Sánchez found the BCBS TPPs arguments compelling and completely disregarded *Sargeants* and *UFCW Local 1776*. **So does this Court**.

(SJ Op. 61-62 (emphasis added and footnotes omitted).)

Defendants did not move for reconsideration of Judge Kugler's summary

judgment opinion, and accordingly it is now the law of the case.[6]

D. Defendants Essentially Propose a Rule of "No Damages"

Aside from the fact that the defense failed to propose the cost of so-called replacement drugs, thus making it impossible for the jury to calculate the difference without completely speculating, the Defendants' position would essentially create a rule of no damages for these types of claims since the patients needed a treatment for their condition.[7] This should not and cannot be the law.

E. Defendants Successfully Opposed Discovery Regarding Other Drugs and Cannot Support their Replacement Drugs Theory with Admissible Evidence

During discovery, Defendants successfully opposed discovery regarding other hypertension medications (such as the drugs which comprise their "replacement drug" theory of damages). (*See, e.g.,* Dkt. No. 303, at 3 ("Plainitffs' request for discovery regarding other products … is DENIED."; *see also* Nov. 20, 2019 CMC Tr., at 16:17-20 ("Thus, the burden and expense of the non-Valsartan discovery is disproportional to its importance and relevance.").

[6] Defendants' *Celexa* case likewise is inapposite as a RICO case, and also because the damages expert there explicitly put forward a damages methodlogy using "regression models, simulating 'but-for' scenarios to predict the value of prescriptions induced by [the defendant's] misconduct." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 325 F.R.D. 529, 540 (D. Mass. 2017). In other words, the plaintiffs there did not seek benefit-of-the-bargain damages at all.

[7] Imagine a purchase of listeria-tainted ice cream for a child's birthday party. The defendant would argue that the the plaintiff would have purchased ice cream for the party in any event, and is therefore owed no damages.

In addition, Defendants' experts do not identifty the specific replacement therapies and associated prices therewith, and thus any testimony sought to be presented to the jury on this is impermissible. *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) ("expert's opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation" (citations and internal quotations omitted)). With no admissible evidence, Defendants would be inviting the jury to render a speculative verdict.

Having successfully contested discovery and having failed to disclose experts who identify the replacements or their prices, it would be manifestly unjust for Defendants to assert that pricing of other unnamed products and treatments is now essential to the appropriate modeling of damages.

III. CONCLUSION

Defendants' "replacement drugs" theory is contrary to applicable law, this Court's prior decisions, does not "fit" the case, and is unsupported by admissible evidence that would save the jury from having to speculate and make up the evidence needed to apply that argument. This would mislead, confuse, and distract the jury with irrelevant and unduly prejudicial argument, evidence, and testimony about other products which are not at issue and not part of how the jury will be instructed to calculate damages. Fed. R. Evid. 401-403. The Court should grant Plaintiffs' MIL 16 on this topic and preclude Defendants from injecting this issue into the trial.

Dated: August 15, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 15, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s John R. Davis